K083266
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510(k) SUMMARY

Applicant:

W. L. Gore & Associates, Inc.
301 Airport Road
Elkton, Maryland 21922 USA

MAR 2 7 2009

Contact:

Barbara L. Smith
Regulatory Associate

Common Name: Fistula Plug

Classification: 21CFR878.3300

Classification Name: Surgical Mesh

FDA product code: FTL

Device Class: II

Device Predicates:

1. 510(k) #: K033671
   Predicate Device name: Gore Bioabsorbable Mesh
   Manufacturer: W. L. Gore & Associates, Inc.

2. 510(k) #: K050337
   Predicate Device Name: SIS Fistula Plug
   Manufacturer: Cook Biotech Incorporated

Device Description:

The GORE BIO-A™ Fistula Plug is a surgical mesh supplied in a preformed three-dimensional shape (disk with attached tubes) and comprised of a porous structure of synthetic bioabsorbable PGA/TMC copolymer fiber, degraded via a combination of hydrolytic and enzymatic pathways. The PGA:TMC material is bioabsorbable and has been demonstrated to be both biocompatible and non-antigenic. It is not derived from animal or human tissues. The GORE BIO-A™ Fistula Plug is a tailorable, bioabsorbable material intended to reinforce soft tissue during the phases of wound healing by initially occupying the fistula defect and at the

same time eliciting a physiological tissue response which fills the fistula defect with native tissue as the fistula plug gradually absorbs. The GORE BIO-A™ Fistula Plug is provided sterile for single use only.

Statement of Intended Use:

The GORE BIO-A™ Fistula Plug device is intended for use in the reinforcement of soft tissue for repair of anorectal fistulas.

Technological Characteristics:

The GORE BIO-A™ Fistula Plug device is comprised of the same material, technology and three-dimensional disk with tubes mesh design as the predicate GORE Bioabsorbable Mesh hernia plug device. The indications for use and performance of the GORE BIO-A™ Fistula Plug are substantially equivalent to the predicate Cook SIS Fistula Plug.

Substantial Equivalence:

A variety of in vitro and in vivo tests and comparisons demonstrate that the GORE BIO-A™ Fistula Plug device is substantially equivalent in intended/indications for use, performance, materials and technology to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

W.L. Gore & Associates, Inc.
% Ms. Barbara L. Smith
Regulatory Associate
301 Airport Road
Elkton, Maryland 21922

MAR 2 7 2009

Re: K083266
Trade/Device Name: GORE BIO-A™ Fistula Plug
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: March 18, 2009
Received: March 19, 2009

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Fed-ral Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083266

Indications for Use

510(k) Number (if known):_____

Device Name: GORE BIO-A™ Fistula Plug

Indications for Use:

The GORE Fistula Plug device is intended for use in the reinforcement of soft tissue for the repair of anorectal fistulas.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MXM 3/27/09

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K083266